

REMARKS/ARGUMENTS

Reconsideration of this application is respectfully requested in view of the foregoing amendments and discussion presented herein. Claims 64-67, 70-81, and 84-92 are pending in the present application. Claims 68, 69, and 82-83 have been withdrawn. Claims 93-98 have been cancelled.

1. Rejection of Claims 64-67, 70-81, and 84-92 under 35 U.S.C. § 103(a).

Claims 64-67, 70-81, and 84-92 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Swaminathan (U.S. No. 6,517,533). Such rejections are traversed as follows:

Independent method Claim 64 recites, among other steps, inserting a catheter assembly into the general proximity of the target prostate gland, placing the distal end of the inserted catheter assembly in a space between the rectum and the prostate gland, inflating an inflatable member of the catheter assembly between the prostate gland and the rectal wall, and initiating and conducting treatment of the prostate gland tissue.

Independent method Claim 79 similarly recites: placing the distal end of said inserted catheter assembly at an edge between the target tissue site and a sensitive healthy tissue or non-targeted site, inflating an inflatable member of the catheter assembly between the target tissue and non-targeted tissue to physically displace the target tissue from the non-targeted tissue, and initiating and conducting treatment of the target tissue once the inflatable member is inflated.

Independent method Claim 88 recites, among other steps, placing the distal end of an inserted catheter assembly in a space between the rectum and the prostate gland, and inflating an inflatable member of the catheter assembly between the prostate gland and the rectal wall.

As explained on page 3 of the present Office Action, "Swaminathan does not specifically point out the steps of placing the distal end of catheter (90) in a space between the rectum and the prostate gland nor between the target tissue site and a sensitive healthy tissue." To cure this deficiency, the Office Action states that "it would

have been obvious matter of design choice to used the Swaminathan's catheter assembly performing the steps of placing the distal end of the catheter (90) in a space between the rectum and the prostate gland or between the target tissue site and a sensitive healthy tissue." (emphasis added).

As provided in M.P.E.P. § 2142, the Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1396 (2007) noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. "[R]ejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). Furthermore, the Examiner must make "explicit" this rationale of "the apparent reason to combine the known elements in the fashion claimed," including a detailed explanation of "the effects of demands known to the design community or present in the marketplace" and "the background knowledge possessed by a person having ordinary skill in the art" (*KSR*, page 14).

The Examiner's reasoning that the use of the Swaminathan device was obvious because it "would have been obvious matter of design choice" is the model of a conclusory statement, and is accordingly impermissible under *KSR* and the MPEP. The Examiner has provided no articulated reasoning as to how such a use would be a mere design choice among a physician or one skilled in the art of using such a device. There is no discussion in the cited references, or provided in the Office Action itself, of whether the Swaminathan device is even capable of being used or administered in a complicated anatomical region such as that located between the prostate gland and the rectum, particularly when considering that the device would need to be administered through means other than intra-oral, intra-vaginal, intra-rectal, or intra-urethral delivery, which would require significant medical expertise to perform.

Furthermore, Applicants contend that the Examiner's use of the "design choice" rationale, as applied to the present claims, is improper. Under MPEP § 2144.04, if the

facts in a prior legal decision are sufficiently similar to those in an application under examination, the Examiner may use the rationale used by the court. The only discussion of "design choice" that the Applicants were able to find in the MPEP was §2144.04(VI)(C), but only insofar with regard to a rearrangement of parts (*In re Kuhle*, 526 F.2d 553, 188 USPQ 7 (CCPA 1975) (the particular placement of a contact in a conductivity measuring device was held to be an obvious matter of design choice)). Because the presently rejected claims are directed to methods, not "parts", Applicants find the instant case dissimilar to the facts cited by the court and MPEP. Furthermore, even if one were to construe "method steps" as "parts", the Examiner's manipulation of the Swaminathan reference cannot represent a "rearrangement of parts," because the cited reference fails to disclose all of the parts (method steps) disclosed in the rejected claims (e.g. placing the distal end of said inserted catheter assembly in a space between the rectum and the prostate gland).

Yet further, "the mere fact that [one] in the art could rearrange the parts of the reference device to meet the terms of the claims... is not by itself sufficient to support a finding of obviousness. The prior art must provide a motivation or reason for [one] in the art, without the benefit of the [applicant's] specification, to make the necessary changes in the reference device." MPEP §2144.04(VI)(C), *Ex parte Chicago Rawhide Mfg. Co.*, 223 USPQ 351, 353 (Bd. Pat. App. & Inter. 1984). Such motivation or reason has not been shown nor taught, as the Swaminathan reference is near absent any description of anatomy. Even more, Applicants failed to find any discussion anywhere in the Swaminathan reference of treating the prostate gland (a word search of the term "prostate" found no occurrences), nonetheless placing the distal end of the inserted catheter assembly in a space between the rectum and the prostate gland, as recited in Claim 64. Furthermore, no discussion was found for inflating an inflatable member to physically displace the target tissue from the non-targeted tissue, as recited in claim 79. In fact, the only description of treatment within the body that the Applicants were able to find in Swaminathan was at col. 2 lines 24-34, stating "clinical situations may be

vascular or nonvascular applications, and may include coronary or non-coronary applications."

Claim 88, in addition to the above patentable steps, further recites the step of initiating and conducting radiation treatment of the prostate gland tissue. Swaminathan discloses a cryotherapy (i.e., "therapeutic use of cold") device. Thus, it does not teach of, nor is capable of, conducting radiation treatment. This element was ignored in the present Office Action. Under MPEP 2143.03 "all words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970).

Accordingly, independent Claims 64, 79, and 88 are allowable over the cited art. Under MPEP 2143.03, if an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). Hence, Claims 65-67, 70-78, 80-81, 84-87, and 89-92 are allowable. In addition, 65-67, 70-78, 80-81, 84-87, and 89-92 also recite limitations that are not found in the cited reference.

For example, Claim 72 recites, among other elements, inflating or circulating a fluid through the catheter assembly that is below the normal body temperature during the treatment of the prostate gland by thermotherapy, wherein the treatment comprises heating the prostate gland. This allows the fluid to cool surrounding tissue during thermal therapy treatment that is heating the target site. Swaminathan, in contrast, discloses a cryotherapy device that uses a liquid to cryogenically cool and treat surrounding tissue. The Swaminathan reference does not teach or suggest any therapeutic heating of a target tissue, particularly since the device is configured for cryotherapy, e.g. cooling tissue. Again, this element was ignored in the pending Office Action.

For example, Claim 73 recites the steps of inflating an inflatable member with a gas to physically displace the prostate from the rectal wall and form an acoustic barrier to protect rectal wall or surrounding tissue, and initiating and completing ultrasonic

treatment of the prostate gland. As explained above, Swaminathan does not mention treatment of the prostate, particularly displacing the prostate from the rectal wall. In addition, neither of the steps of forming an acoustic barrier nor initiating ultrasonic treatment are taught or suggested by the cited art.

Claim 84 recites, among other elements, inflating an inflatable member with a gas to physically displace the target tissue from the sensitive tissue and form an acoustic barrier, initiating and completing ultrasonic treatment of the target tissue, and replacing the gas within the inflatable member and the catheter assembly with a liquid after the conclusion of the ultrasonic treatment of the target tissue. As explained above, formation of an acoustic barrier and use of ultrasonic treatment are not taught nor suggested by Swaminathan. In addition, Swaminathan is void any discussion of use of a gas to physically displace target tissue from sensitive tissue, nor replacing the gas with a liquid.

Accordingly, the rejection of Claims 65-67, 70-78, 80-81, 84-87, and 89-92 under §103 in view of Swaminathan is improper, and should be removed.

2. Amendments Made Without Prejudice or Estoppel.

Notwithstanding the amendments made and accompanying traversing remarks provided above, Applicants have made these amendments in order to expedite allowance of the currently pending subject matter. However, Applicants do not acquiesce in the original ground for rejection with respect to the original form of these claims. These amendments have been made without any prejudice, waiver, or estoppel, and without forfeiture or dedication to the public, with respect to the original subject matter of the claims as originally filed or in their form immediately preceding these amendments. Applicants reserve the right to pursue the original scope of these claims in the future, such as through continuation practice, for example.

3. Conclusion.

Based on the foregoing, Applicants respectfully request that the various grounds for rejection in the Office Action be reconsidered and withdrawn with respect to the

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presently amended form of the claims, and that a Notice of Allowance be issued for the present application to pass to issuance.

Date: May 27, 2008

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'J. P. O'Banion', written in a cursive style.

John P. O'Banion, Reg. No. 33,201
M. Robyn Carrillo, Reg. No. 47,474
Robert F. Kramer, Reg. No. 51,242
O'BANION & RITCHEY LLP
400 Capitol Mall, Suite 1550
Sacramento, CA 95814
(916) 498-1010